METHOD FOR TREATING GASTROINTESTINAL DISORDER

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims benefit from U.S. Provisional Application No. 60/606,521 filed on Sep. 2, 2004, U.S. Provisional Application No. 60/666,317 filed on Mar. 30, 2005, and U.S. Provisional Application No. 60/666,593 filed on Mar. 31, 2005 in the United States Patent and Trademark Office, the disclosures of which are incorporated herein in their entirety by reference.

TECHNICAL FIELD

The present invention relates to a method and composition for the long-term treatment of gastrointestinal disorders in a human subject.

The present invention also relates to a method and composition for the treatment of gastrointestinal disorders in both male and female human subject.

The present invention further relates to a method and composition for the treatment of gastrointestinal disorders in a human subject aged 65 years and older.

Furthermore, the present invention relates to a method and composition for the improvement of quality of life in a human subject with gastrointestinal disorders.

BACKGROUND ART

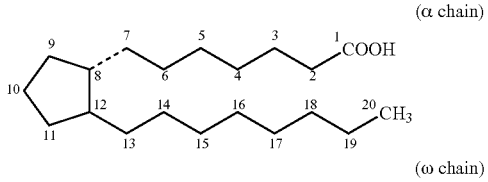
Constipation is generally defined as infrequent and difficult passage of stool. Medical reporting estimates that one of every 50 people in the United States suffers from constipation. That is, one of the most common disorders among Americans. Constipation is more likely to affect females than males and more likely to occur in older adults, showing an exponential increase after the age of 65. The actual occurrence of constipation is likely higher than reported, as many individuals suffer at home without seeking professional care.

Although in some instances constipation may be caused by obstruction, most constipation can be associated with factors such as a diet low in soluble and insoluble fibers, inadequate exercise, medication use (in particular, opiate analgesics, anticholinergic antidepressants, antihistamines, and vinca alkaloids), bowel disorders, neuromuscular disorders, metabolic disorders, poor abdominal pressure or muscular atony.

A precise quantitative definition of constipation has been difficult to establish due to the wide range of perceived "normal" bowel habits, as well as the diverse array of symptoms and signs associated with constipation. The FDA has recognized a need for prescriptive treatment of occasional constipation.

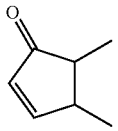
Prostaglandins (hereinafter, referred to as PGs) are members of class of organic carboxylic acids, which are contained in tissues or organs of human or other mammals, and exhibit a wide range of physiological activity. PGs found in nature (primary PGs) generally have a prostanoic acid skeleton as shown in the formula (A):

(A)

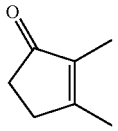


PGs are classified into several types according to the structure and substituents on the five-membered ring, for example,

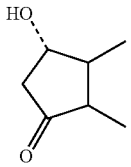
Prostaglandins of the A series (PGAs);



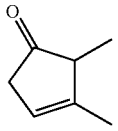
Prostaglandins of the B series (PGBs);



Prostaglandins of the C series (PGCs);



Prostaglandins of the D series (PGDs);



Prostaglandins of the E series (PGEs);